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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,969	05/08/2001	Randolph J. Noelle	037003-0280613	1327

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/849,96	Applicant(s) NOREC
	Examiner GAMBEL	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 5/9/03; 7/21/03

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1, 4-10, 12-20

4a) Of the above claim(s) _____ is/are withdrawn from consideration

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 1, 4-10, 12-20

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

PAPER NO. 12

DETAILED ACTION

1.Applicant's amendment, filed 5/9/03 (Paper No. 11), has been entered.
Claims 2, 3 and 11 have been canceled.
Claims 1, 4, 8 and 9 have been amended.
Claims 12-20 have been added.

Claims 1, 4-10 and 12-20 are pending and being acted upon presently.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 5/9/03 (Paper No. 11).
The rejections of record can be found in the previous Office Action (Paper No. 9).

3. Again, applicant should amend the first line of the specification to update the status of the priority documents.

For example, USSN 09/080,349 I s now U.S. Patent No. 6,328,964 and USSN 09/481,735 is now U.S. Patent No. 5,833,987.

4. In view of the applicant's Statement Deleting Inventors Under 37 CFR 1.648(b), filed 5/9/03 (Paper No. 11); the inventorship in this nonprovisional application has been changed by the deletion of George Classen.

The sole inventor of the instant application is Randolph Noelle.

5. Applicant's amended claims, filed 5/9/03 (Paper No. 11), have obviated the previous rejections under 35 U.S.C. § 112, first paragraph, written description and enablement with respect to the recitation of "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions".

6. Claims 1 and 4-10 are rejected under 35 U.S.C. § 102(e) as being anticipated by Noelle et al. (U.S. Patent No. 5,683,693) (see entire document) for the reasons of record set forth in Paper No. 9.

Applicant's arguments, filed 5/9/03 (Paper No. 11), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that the '693 patent does not describe administering a gp39 antagonist to inhibit or prevent a T cell mediated autoimmune response associated with type I diabetes, but rather is directed towards inducing tolerance to transplanted allogeneic or xenogeneic cells.

In contrast to applicant's assertions and as pointed out previously, Noelle et al. teach the use of gp39-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 5-7, Antibodies) to treat the autoimmune disease diabetes (see entire document, including column 11, Uses of the Methods of Invention). Here, '593 discloses that the referenced method includes comprising administering to a subject in need of treatment: (1) allogeneic or xenogeneic cells which express donor antigens, (2) an antagonist of a molecule expressed on recipient T cells which mediate contact-dependent helper effector function, such as a gp39 antagonist (e.g. anti-gp39 antibody) and (3) donor pancreatic islet cells.

Given the inhibitory properties of such gp39-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases, including diabetes with gp39-specific / CD40L-specific antibodies.

Further it is noted that the claimed methods recite "comprising" which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03.

Applicant's arguments are not found persuasive.

7. Claims 1 and 4-10 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 5,993,816) (see entire document) for the reasons of record set forth in Paper No. 9.

Applicant's arguments, filed 5/9/03 (Paper No. 11), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that the '816 patent relates to using a gp39 antagonist to inhibit B cell activation and humoral immune responses. Applicant notes Type I diabetes is mediated primarily through a T cell mediated cellular autoimmunity which is opposed to the humoral immune mechanism, which is distinct from the teachings of the '816 patent.

In contrast to applicant's assertions and as pointed out previously, Lederman et al. teach the use of 5C8-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 7-8) to treat autoimmune diseases including diabetes (see column 11, paragraph 5). Given the inhibitory properties of such 5C8-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat Type I diabetes with of 5C8-specific / CD40L-specific antibodies.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

8. Claims 1 and 4- 10 and newly submitted claims 12-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Noelle et al. (U.S. Patent No. 5,683,693) AND/OR Lederman et al. (U.S. Patent No. 5,993,816) in view of Noelle et al. (U.S. Patent No. 5,747,037) for the reasons of record set forth in Paper No. 9.

Applicant's arguments, filed 5/9/03 (Paper No. 11), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submits that neither the '693 patent of Noelle nor the '816 patent of Lederman et al. Describe or suggest the claimed method of preventing or inhibiting T cell mediated cellular immune responses associated with Type I diabetes. Accordingly, the claims are not rendered obvious by the disclosure of the 24-31 and 89-76 antibodies in U.S. Patent No. 5,747,037.

Applicant's arguments and the examiner's rebuttal concerning the teachings of Noelle et al. ('693) and Lederman et al. are set forth above.

As pointed out previously, Noelle et al. ('037) teach the particular 24-31 and 89-76 CD40L-specific antibodies encompassed by the claimed methods, including recombinant forms thereof as well as their use as therapeutic antagonists in inhibiting various immune responses (see entire document, including Detailed Description of the Invention).

Given the antagonistic properties of the particular 24-31 and 89-76 CD40L-specific antibodies taught by Noelle et al. ('037), the ordinary artisan would have been motivated to substitute these CD40L antagonists into the methods of treating autoimmune diseases such as diabetes, as taught by Noelle et al.('693) and Lederman, given their inhibitory properties were consistent with the antagonistic CD40L-specific antibodies taught by the prior art. Noelle et al. ('693), Noelle et al. ('037) and Lederman et al. All teach the advantages of anti-CD40L antibodies to inhibit immune responses by targeting the CD40L on T helper cells in therapeutic modalities of immunosuppression at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Given applicant's statements in conjunction with the amended claims, filed 5/9/03 (Paper No. 11), which distinguish the instant claims drawn to Type I diabetes from the claims of copending USSN 09/223,634 and U.S. Patent No. 6,328,964; the previous provisional / non-provisional rejections under the judicially created doctrine of obviousness-type double patenting have been withdrawn.

10. No claim allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
July 21, 2003